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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/357,704	07/20/1999	NEIL H. BANDER	242/024	9622

26161 7590 07/09/2004

FISH & RICHARDSON PC
225 FRANKLIN ST
BOSTON, MA 02110

EXAMINER	
NICKOL, GARY B	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 07/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/357,704	BANDER, NEIL H.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *69-80,124-127,129,130,136-173 and 186-189* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *69-80,124-127,129,130,136-173 and 186-189* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Bander, N.

Date of priority: 05/06/1996

Response to Amendment

The Amendment filed April 14, 2004 in response to the Office Action of 12/12/2003 is acknowledged and has been entered.

Claims 69-80, 124-127, 129-130, 136-173, 186-189 are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Rejections Maintained:

Claims 69-80, 124-127, 129-130, 136-173, and 186-189 remain rejected under 35 USC 112, 1st paragraph, scope of enablement for the reasons of record with regards to the prevention of prostate cancer. Applicants argue that the amendments to the claims obviate this rejection. This argument has been considered but is not found persuasive. To obviate this rejection, Applicants should review the interview summary mailed 05/26/04, which discussed the present rejection.

New Rejection/Re-instatement

Claims 69-80, 124-127, 129-130, 136-173, 186-189 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As set forth previously (Non-final Action mailed 1-23-2003), the written description in this case only sets forth methods encompassing an antibody or antigen binding portion thereof which binds to the extracellular domain of prostate specific membrane antigen (PSMA), **or** monoclonal antibodies selected from the group consisting of an E99, a J415, a J533, and a J591. Thus, the written description is not commensurate in scope with the claims drawn to an antibody or antigen binding portion thereof which **competes for binding** to prostate specific membrane antigen (PSMA) with a monoclonal antibody selected from the group consisting of an E99, a J415, a J533, and a J591 monoclonal antibody.

Applicant's argue that specification teaches that there are two types of antibodies disclosed in the specification: those that compete for binding with another anti-PSMA antibody, e.g., one of four specific antibodies made, and those that do not compete for binding with the subject antibodies. Specifically, applicants argue that the specification (page 27, lines 26-35) provides an embodiment where two antibodies were being described that it is preferable, but not necessary, that the second biological agent does not compete for binding with the first. See page 27, lines 26-35 which provides that "the prodrug activator is conjugated with a second biological

agent according to the invention, preferably one which binds to a noncompeting site on the PSMA molecule". Thus, Applicants point out that the disclosure is *not* limited to and does not require a noncompeting antibody, but only that a non-competing antibody is preferred.

This argument has been considered but is not found persuasive as it appears that the alleged support has been taken out of context. The passage that applicants refer to pertains to biological agents conjugated to prodrugs- such as antibody conjugates. Prodrugs are inactive drugs. In the instant case, the conjugated prodrug becomes activated (page 27, line 28) "only when in *close* proximity with a prodrug activator". Thus, the fact that a preferred embodiment of a prodrug/prodrug activator scenario is one in which the biological agent binds in close proximity to one another (i.e...to non-competing sites) on the antigen is not surprising given the fact that said activators must be nearby to activate the prodrug. In contrast, however, it would be surprising and quite complex to conceive of administering biological agents conjugated to prodrugs and or prodrug activators that bind to *competing* sites on an antigen because such sites are indicative of the same epitope. Hence, the administration of biological agents (for the purposes of activating a prodrug) that bind to competing sites would effectively reduce the probability that a prodrug would be activated. Thus, applicants alleged support for the inclusion of "competing" sites is not found persuasive because there is no contextual nexus that adequately provides support for the newly amended claims. This reasoning further extends to applicants arguments that the specification discloses what constitutes a competing site and what constitutes a non-competing site by stating that "whether two biological agents bind to competing or non-competing sites can be determined by conventional competition binding

assays." (page 28, lines 6-10). Again, such passage refers to the administration of *non-competing* antibodies. "Thus, for example, the first biological agent can be one of J591, J533, and E99, and the second biological agent can be J415. Alternatively, the first biological agent can be J415, and the second biological agent can be one of J591, J533, and E99." (page 28, lines 6+). Moreover, the specification teaches (page 28, lines 1+) that J591, J533, and E99 bind to competing sites while monoclonal antibody J415 binds to a binding site which is noncompeting with the site to which J591, J533, and E99 bind. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

No claim is allowed.

All other rejections and or objections are withdrawn in view of applicant's amendments and arguments there to.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.
Primary Examiner
Art Unit 1642

07/07/04

GARY B. NICKOL, PH.D.
PRIMARY EXAMINER